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Display Date 10-28-04
Publication Date 10-29-04
Certifier J. Cook

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0453]

Draft Revised Compliance Policy Guide "Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act (CPG 7119.05);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revision of the compliance policy guide (CPG) entitled "Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act." The draft CPG provides guidance on the applicability of the Federal Import Milk Act (FIMA) to imported milk and cream.

DATES: Submit written or electronic comments on the draft revised CPG by [*insert date 30 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome any time.

ADDRESSES: Submit written requests for single copies of the draft revision of the CPG entitled "Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act" to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville,

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MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Esther Lazar, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1485, FAX: 301–436–2632.

SUPPLEMENTARY INFORMATION:

I. Background

The FIMA (21 U.S.C. 141 *et seq.*) prohibits the importation into the United States of milk and cream without a valid permit from the Secretary of Health and Human Services. FDA is revising the CPG to clarify and update its policy regarding which dairy products require permits under the FIMA. As explained in the draft CPG, FDA intends to consider the following dairy products to be subject to the FIMA's permit requirement for importation into the United States:

- Milk, lowfat milk, skim milk, fortified milk, flavored milk, concentrated milk, evaporated milk, sweetened condensed milk, ultra filtered milk.
- Cream, half-and-half, heavy cream, light cream, and light whipping cream.

FDA does not intend to require a FIMA permit for the following dairy products:

- Sour cream, cultured milk, acidified milk, yogurt, cheese, ice cream, and eggnog.
- Dried milk, nonfat dry milk, nonfat dry milk fortified with vitamins A and D, and other dehydrated milk products.

• Any dairy product for which a permit is otherwise required, if it has been processed and packaged in hermetically sealed containers so as to be commercially sterile in accordance with the requirements of 21 CFR 108.35 and 21 CFR part 113.

FDA has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). The draft guidance is being issued as a level 1 draft guidance consistent with GGPs. The draft revised CPG represents the agency's current thinking on the applicability of the FIMA to imported milk and cream. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statues and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4.p.m., Monday through Friday.

III. Electronic Access

A copy of the draft revised CPG may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home

page includes the draft revised CPG and may be accessed at *http://www.fda.gov/ora* under "Compliance Reference."

Dated: 10-22-04
October 22, 2004.

John Marzilli
for

John Marzilli,
Acting Associate Commissioner for Regulatory Affairs.

JS 10-25-04

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S